IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI`I

PATRICIA SEGOVIA, INDIVIDUALLY and as ADMINISTRATOR OF THE ESTATE OF THOMAS SEGOVIA, SR., DECEASED and GARY A. POWELL, EXECUTIVE DIRECTOR OF THE CAREGIVER FOUNDATION, INC., as SPECIAL ADMINISTRATOR, Plaintiffs, vs. BRISTOL-MYERS SQUIBB COMPANY and PFIZER, INC., Defendants.	Civil No. 15-00519 DKW-RLP **MEMORANDUM IN SUPPORT OF MOTION**

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I. INTRODUCTION

Plaintiffs' wrongful death action alleges that Thomas Segovia, Sr. ("Mr. Segovia") died on July 27, 2014, after experiencing a hemorrhagic stroke in December 2013. They allege Mr. Segovia died as a result of taking Eliquis, an anti-coagulant developed by Defendants to help prevent strokes in patients with atrial fibrillation. Plaintiffs claim that Defendants failed to warn physicians that Eliquis could cause bleeding, even though the Eliquis label approved by the U.S. Food & Drug Administration ("FDA") has warned since December 2012 (more than ten months before Mr. Segovia started taking Eliquis) that Eliquis "increases the risk of bleeding and can cause serious, potentially fatal bleeding." *See* Request for Judicial Notice ("RJN"), Ex. B.

Plaintiffs assert three causes of action: (1) strict liability in tort, (2) manufacturing and design defect, and (3) negligence and gross negligence. Regardless of what Plaintiffs call their causes of action, however, at bottom Plaintiffs allege little more than that Defendants failed to warn that Eliquis could increase the risk of bleeding, notwithstanding the fact that the label expressly warned of the type of injury Mr. Segovia allegedly sustained. Plaintiffs fail to state a claim for a myriad of reasons.

First, Plaintiffs allege a manufacturing defect claim, but they fail to plead the facts required to support such a claim. Second, Plaintiffs allege a design defect claim, but they are foreclosed from bringing such a claim to the extent it is based on the chemical composition or other aspects of the design of Eliquis. That is so because, under the Restatement (Second) of Torts (relevant provisions of which Hawaii's courts have adopted), plaintiffs cannot assert design defect claims for "unavoidably unsafe" products, such as prescription medications, except to the extent plaintiffs challenge the adequacy of the medication's label. Third, some of Plaintiffs' claims appear founded on allegations of fraud. As such, under Fed. R. Civ. P. 9(b), Plaintiffs are required to plead their claims with specificity, which they have not done. Finally, although Plaintiffs purport to seek punitive damages, Plaintiffs fail to allege facts that would give rise to such damages. This collection of defects in Plaintiffs' First Amended Complaint calls for dismissal of all their claims, except to the extent their strict liability and negligence causes of action implicate Defendants' alleged failure to warn.

II. FACTUAL BACKGROUND

A. Eliquis (apixaban)

Eliquis is a prescription anti-coagulant (blood thinner), which reduces the risk of blood clots by blocking a clotting factor known as Factor Xa, and which was developed and is marketed jointly by Defendants.

In December 2012, FDA approved Eliquis to reduce the risk of stroke and blood clots in people who have atrial fibrillation, a type of irregular heartbeat that can cause blood clots and lead to a stroke. *See* Ex. G, First Amended Complaint ("FAC") Dkt. 8 at ¶¶ 23-24. From the outset, the Eliquis label warned physicians that Eliquis "increases the risk of bleeding and can cause serious, potentially fatal, bleeding." RJN, Ex. B.[1] In March 2014 and August 2014, FDA approved Eliquis for additional uses and approved the language quoted above on both occasions.

The Complaint alleges that Decedent was prescribed Eliquis for treatment of his atrial fibrillation for approximately two months before suffering a hemorrhagic stroke on December 20, 2013, and that he died on July 27, 2014. FAC ¶¶ 10-12.

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[1] Because FDA communications, approvals and labels are matters of public record that can be "accurately and readily determined from sources whose accuracy cannot reasonably be questioned" and thus are "not subject to reasonable dispute," Fed. R. Evid. 201(b), the court may take judicial notice of them without converting this motion into one for summary judgment. *See Hancock v. Kulana Partners, LLC*, 992 F. Supp. 2d 1053, 1058 (D. Haw. 2014); *Hawai`i Coal. for Health v. Hawai`i, Dep't of Human Serv.*, 576 F. Supp. 2d 1114, 1119 n.3 (D. Haw. 2008), *aff'd*, 365 Fed. Appx. 874 (9th Cir. 2010); *see also Wilson v. Amneal Pharms., L.L.C.*, No. 1:13-cv-00333, 2013 WL 6909930, *5-7 (D. Idaho Dec. 31, 2013) (taking judicial notice of FDA-approved labels where cause of action for failure to warn was dependent upon the label, and referenced by plaintiff's allegation that defendant failed to give proper notice and instructions as to the defects and dangers of the drug.)

B. Procedural Posture

Plaintiff Patricia Segovia initiated this lawsuit by filing a Complaint [Dkt. 1] in this Court on December 15, 2015. On December 18, 2015, Plaintiff filed a First Amended Complaint. Among the changes to the Complaint, she now brings the claims in her individual capacity and as Administrator of the Estate of Thomas Segovia, Sr., Deceased. *See* Ex. G, FAC. The Amended Complaint also includes Plaintiff "Gary A. Powell, Executive Director of the Caregiver Foundation, Inc., as Special Administrator." *Id.* Ms. Segovia and Mr. Powell hereinafter will be referred to collectively as "Plaintiffs."

III. LEGAL ANALYSIS

A. Motion to Dismiss Under Fed. R. Civ. P. 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a "short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555, 127 S. Ct. 1955, 1964-65, 167 L. Ed. 2d 929 (2007) (citations omitted) ("*Twombly*"). While a complaint does not need detailed factual allegations to survive a Rule 12(b)(6) motion to dismiss, a plaintiff's obligation to provide the "grounds" of her "entitle[ment] to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not suffice. *See id.*

Indeed, dismissal under Fed. R. Civ. P. 12(b) is required when a plaintiff fails to set forth "enough facts to state a claim [for] relief that is plausible on its face." *Twombly*, 550 U.S. at 570. In adopting the plausibility standard for evaluating federal complaints, the Supreme Court held that "factual allegations must be enough to raise a right of relief above the speculative level." *Id.* at 555, 561-63. In *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79, 129 S. Ct. 1937, 1939, 173 L. Ed. 2d 868 (2009) ("*Iqbal*"), the Court explained that a court must identify which statements in the complaint are factual allegations and which are legal conclusions, even if cast in the form of factual allegations. *See id.* at 681.

Conclusory allegations of law, unwarranted deductions of fact, and unreasonable inferences are insufficient to defeat a motion to dismiss. *See Wada v. Aloha King, LLC*, --- F.Supp.3d ----, No. 14-00275, 2015 WL 9459898, at *6-7 (D. Haw. Dec. 23, 2015); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1029 (D. Haw. 2014). Additionally, the court need not accept as true allegations that contradict matters properly subject to judicial notice. *Wada*, 2015 WL 9459898, at *6. After setting aside conclusory legal allegations, formulaic factual recitations that merely regurgitate the elements of a claim, and unreasonable factual inferences, the court, drawing "on its judicial experience and common sense," must decide, in the specific context of the case, whether the factual allegations, if assumed true, allege a plausible claim. *Iqbal*, 556 U.S. at 679.

Dismissal is proper either where there is a "lack of a cognizable legal theory" or "insufficient facts under a cognizable legal theory." *S.E.C. v. Lyndon*, 27 F. Supp. 3d 1062, 1072 (D. Haw. 2014). Here, Plaintiffs' Complaint is replete with boilerplate allegations, conclusory statements, and unsupported legal conclusions that do not satisfy this "plausibility" requirement.

B. Plaintiffs' Manufacturing Defect Claims Are Not Supported by Sufficient Facts and Should Be Dismissed.

Plaintiffs allege manufacturing defect claims with respect to Eliquis in connection with each cause of action, under the auspices of strict liability and negligence. *See, e.g.*, Ex. G, FAC ¶¶ 61, 79, 102. No matter on which theory of liability Plaintiffs rely, all of these manufacturing claims fail and should be dismissed.

1. Plaintiffs' Strict Liability Manufacturing Defect Claims (Counts I and II) Fail to Allege Facts Sufficient to Support a Claim for Relief.

Plaintiffs' strict liability manufacturing defect claims do not allege any facts sufficient to establish that the Eliquis Mr. Segovia took departed from the manufacturers' design and that any such departure could and did cause his injury. Under Hawai`i law, to prove a claim of manufacturing defect, a plaintiff must prove: (1) the product as manufactured or distributed was different from the manufacturer's intended result; (2) that difference made the product dangerously defective for its intended or reasonably foreseeable use (or misuse); and (3) that

difference was a legal cause of injury to plaintiff. Hawai`i Civil Jury Instructions, Instruction No. 11.5 (Defective Manufacture – Elements), 1999 edition.

A strict liability manufacturing defect claim hinges on proof that "the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product." *Burlington Ins. Co. v. United Coatings Mfg. Co.*, 518 F. Supp. 2d 1241, 1252 (D. Haw. 2007) (quoting Restatement (Third) Of Torts § 2(a), cmt. a). Stated differently, "[a] manufacturing defect occurs when, at the manufacturing stage, the product does not conform to the quality of other products of its kind." *Rodriguez v. Gen. Dynamics Armament & Tech. Prods., Inc.*, 696 F. Supp. 2d 1163, 1179 (D. Haw. 2010) (quoting *Wagatsuma v. Patch*, 10 Haw. App. 547, 564 n.6 (1994)). A plaintiff must establish the product was in a defective condition when it left the hands of the seller or manufacturer. *Dolan v. Hilo Med. Ctr.*, 127 Hawai`i 325, 339 (2012) (citations omitted). A plaintiff alleging a manufacturing defect also must allege proximate causation; that is, "the plaintiff must prove a causal connection between the defect and the plaintiff's injuries." *Id.* (citing *Acoba v. Gen. Tire, Inc.*, 92 Hawai`i 1, 16 (1999)).

Here, Plaintiffs fail to plead *any* facts which, if true, would establish the essential elements of a strict liability manufacturing defect claim, including how the Eliquis Mr. Segovia took departed from the Defendants' design, how any such

difference made the Eliquis he took dangerous, and how that difference caused his injury. Plaintiffs' First and Second Counts, titled "Strict Liability in Tort" and "Manufacturing and Design Defect," both purport to allege manufacturing defect claims but fail to allege any of these elements, which are necessary to a sustain such a claim. *Compare Dolan*, 127 Hawai`i at 339, *with* Ex. G, FAC.

At most, Plaintiffs make two conclusory allegations with respect to the manufacturing of Eliquis, but neither is sufficient to satisfy the necessary elements of departure from an intended design and an increased danger due to that design, which causes a plaintiff's injury. First, Plaintiffs claim a manufacturing defect as a result of an unspecified "defective condition." *See* Ex. G, FAC, Count I, ¶ 61 ("The Eliquis designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants **was manufactured defectively in that Eliquis left the hands of Defendants in a defective condition** and was unreasonably dangerous to its intended users.") (emphasis added). In a different cause of action, Plaintiffs allege in passing that the Eliquis Mr. Segovia took "deviated from product specifications and/or applicable federal requirements …" Ex. G, FAC, Count II, ¶ 79 ("Eliquis was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from product specifications and/or applicable federal requirements, and posed a risk of serious

injury and death."). In neither place do Plaintiffs support their conclusion by identifying a specific deviation from the intended design, how any such deviation made the Eliquis defective or more dangerous, or how that specific defect caused Mr. Segovia's injuries. Plaintiffs' allegations are sweeping, formulaic, and conclusory, and they do not offer sufficient facts to make Plaintiffs' claims plausible under *Twombly* and *Iqbal*. Accordingly, Plaintiffs' claims asserting strict liability manufacturing defect should be dismissed.

2. Plaintiffs' Negligent Manufacturing Defect Claims (Count III) Fail to Allege Facts Sufficient to Support a Claim for Relief.

Similarly, Plaintiffs' negligence-based manufacturing defect claims do not allege any facts sufficient to make it plausible that Defendants breached their duty of care in manufacturing the Eliquis Mr. Segovia took. Under Hawai`i law, a products liability claim based on a negligence theory "has three elements: (1) a duty to anticipate and design against reasonably foreseeable hazards; (2) breach of that duty; and (3) injury proximately [i.e., legally] caused by the breach." *Tabieros v. Clark Equip. Co.*, 85 Hawai`i 336, 370 (1997) (quoting *Wagatsuma*, 10 Haw. App. at 564) (internal quotations omitted). "In negligence, the plaintiff must show that the defendant breached its duty of care, while in strict liability the plaintiff must show that the product was defective because it was unreasonably dangerous." *Wagatsuma*, 10 Haw. App. at 564. "Negligence theory concerns itself with

determining whether the conduct of the defendant was reasonable in view of the foreseeable risk of injury . . ." *Id.*

Here, Plaintiffs' negligence claim predicated on the manufacturing of Eliquis is flawed in several respects. Most importantly, the Complaint lacks plausible factual allegations. Plaintiffs allege in conclusory fashion that Defendants negligently manufactured (Ex. G, FAC, ¶ 102r), produced (*id.*, ¶ 102s), and assembled (*id.*, ¶ 102t) Eliquis in a manner which was dangerous to its users. Yet, Plaintiffs fail to include any facts that establish a plausible foundation for these conclusions.

Courts in this Circuit have held that such conclusory allegations in product liability cases are insufficient to survive a motion to dismiss. *See, e.g.*, *Nimtz v. Cepin*, No. 08cv1294, 2011 WL 831182, at *2-3 (S.D. Cal. Mar. 3, 2011) (dismissing complaint for failure to plead more than "legal conclusions" concerning the elements of a product liability action); *Lucas v. City of Visalia*, 726 F. Supp. 2d 1149, 1155 (E.D. Cal. 2010) (dismissing manufacturing defect claim and holding that the plaintiff must identify and explain how the product deviated from the intended result or design, or how it deviated from other seemingly identical models, and that a bald allegation that the product had "a manufacturing defect" was an insufficient legal conclusion under *Iqbal*). Plaintiffs' Complaint suffers from the same problem as the pleading in *Lucas*: the claims are boilerplate

accusations and stock recitations of the elements, unsupported by any pertinent factual allegations. Accordingly, Plaintiffs' claims plainly fail to satisfy the rigorous pleading requirements of *Iqbal* and *Twombly* and should be dismissed.

C. Plaintiffs' Design Defect Claims Fail to the Extent They Are Based on Eliquis' Chemical Composition.

Plaintiffs' design defect claims also fail to meet the *Twombly*/*Iqbal* standard, to the extent they are based on the chemical composition of Eliquis. Under Hawai`i law, in order to succeed on a strict liability claim for design defect, a plaintiff must prove: (1) a defect in the product which rendered it unreasonably dangerous for its intended or reasonably foreseeable use; and (2) a causal connection between the defect and the plaintiff's injuries. *Tabieros*, 85 Hawai`i at 354. A product may be found to be defectively designed in one of two ways: either in its composition or as a result of insufficient warnings. *See Torres v. N.W. Eng'g Co.*, 86 Hawai`i 383, 397 (1997).

Hawai`i follows the Restatement (Second) of Torts § 402A, however, which provides that medications are "unavoidably unsafe," in that they are incapable of being made safe for their intended and ordinary use. *See* Restatement (Second) of Torts § 402A, comment k; *Larsen v. Pacesetter Sys., Inc.*, 74 Haw. 1, 23-24 (1992). Under Section 402A, a manufacturer of an "unavoidably unsafe product" such as a medication generally cannot be held "strictly liable for the unfortunate consequences stemming from their use." *Forsyth v. Eli Lilly and Co.*, No. 95-

00185, 1998 WL 35152135, at *3 (D. Haw. Jan. 5, 1998); *see Larsen*, 74 Haw. at 24. An "unavoidably unsafe" product is thus not defective or unreasonably dangerous for purposes of strict product liability so long as it is accompanied by proper instructions and warning. *See Larsen*, 74 Haw. at 24; *see also Forsyth*, 1998 WL 35152135, at *3-4. Thus, under Hawai`i law and the Restatement, a plaintiff may assert that the "design" of a medication is defective due to the inadequacy of the warnings that accompanied it, but she may not challenge the chemical composition of the medication or other aspects of the medication's design. *Id.*

Courts in Hawai`i and elsewhere have recognized this distinction between warnings-based and composition-based design defect claims. For example, in *Forsyth*, plaintiffs brought a wrongful death suit against the manufacturer of Prozac for William Forsyth's murder of his wife, June, and his subsequent suicide. They claimed the manufacturer was liable under strict liability and negligence theories because William Forsyth had been prescribed Prozac for his depression shortly before the murder and suicide. *Id.* at *1. Defendants moved for summary judgment on Plaintiffs' design defect claim, alleging that Prozac was an "unavoidably unsafe product" under comment k. *Id.* at *3-4. Defendants further argued that no alternative designs or forms of Prozac could be created without

completely altering the medication. *Id.*[2] Although the court agreed with this analysis, it ultimately denied summary judgment on the warnings-based aspect of the plaintiff's design defect claim because it found there was a "genuine issue of fact as to whether Lilly provided an adequate warning for Prozac." *Id.*

Courts in other states that have adopted the Restatement also have held that only warnings-based design defect claims are viable, while composition-based design defect claims are not. *See Patterson v. Bayer Healthcare Pharms., Inc.*, No. 1:14-cv-01087, 2015 WL 778997, at *9 (E.D. Cal. Feb. 24, 2015) ("Controlling California authority unequivocally prohibits strict liability claims for design defect against manufacturers of prescription drugs.") (citing *Brown v. Super. Ct.*, 44 Cal. 3d 1049, 1069 (1988)); *see also Stanley v. Novartis Pharms. Corp.*, 11 F. Supp. 3d 987, 1003-04 (C.D. Cal. 2014) (granting summary judgment on strict liability design defect claim); *Tucker v. Wright Med. Tech., Inc.*, No. 11-cv-03086, 2013 WL 1149717, at *4-6 (N.D. Cal. Mar. 19, 2013) (collecting cases in accord and dismissing strict liability claim based on design defect as precluded by California law). In *Brown*, the Court pronounced, consistent with comment k, that a

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[2] Eliquis, like Prozac, cannot be modified without changing the medication entirely. *See Forsyth*, 1998 WL 35152135, at *4. The label provides the molecular formula of the apixaban molecule: $C_{25}H_{25}N_5O_4$. *See* RJN, Ex. B, p. 12. Any changes to the molecule would alter the compound and make it a different medication.

manufacturer is not strictly liable for injuries caused by a prescription medication so long as the medication was properly prepared and accompanied by adequate warnings. 44 Cal. 3d 1069. In clarifying why design defect claims must be limited to those narrow avenues of liability, the court explained that "there is no possibility for an alternative design for a drug like DES, which is a scientific constant compounded in accordance with a required formula." 44 Cal. 3d at 1062.[3]

Accordingly, to the extent Plaintiffs assert design defect causes of action, the only viable claims relate to the adequacy of the Eliquis warning, and Plaintiffs' claims should be narrowed accordingly. To the extent Plaintiffs assert other aspects of Defendants' design of Eliquis were defective (under strict liability) or negligent (under their negligence claims), those fail as a matter of law and should be dismissed.[4]

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[3] Defendants also contest Plaintiffs' allegations that the warnings accompanying Eliquis were inadequate, because the label warned that Eliquis "increases the risk of bleeding and can cause serious, potentially fatal bleeding," RJN, Ex. B, before Mr. Segovia ever took the medication. Further, Plaintiffs' failure to warn claims are preempted under *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187 (2009), and their design defect claims are preempted under *Mutual Pharm. Co. v. Bartlett*, 570 U.S. ---, 133 S. Ct. 2466 (2013) and *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 15-3104, slip op. (6th Cir. Dec. 11, 2015). Defendants intend to assert a preemption defense and to challenge these claims later in the litigation.

[4] Courts have found that design defect claims sounding in strict liability or negligence are "functionally synonymous" and are therefore analyzed identically.

(continued...)

D. Plaintiffs' Fraud-Based Allegations of Misrepresentation Fail to Satisfy the Heightened Pleading Standard of Rule 9(b) and Should Be Dismissed.

Rule 9(b) of the Federal Rules of Civil Procedure requires that, when fraud or mistake is alleged, "a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Allegations of fraud must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Harmer Radio & Elec., Inc. v. S & S Fire Apparatus Co.*, No. 10-007000, 2013 WL 3663878, at *3 (D. Haw. July 11, 2013) (quoting *Bly—Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001)). Fraud claims must allege the "time, place, and specific content of the false representations" as well as the parties' identities. *Id.* (citing *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004)); *see also*

(...continued)

See Yates v. Ortho-McNeil-Janssen Pharms., Inc., No. 15-3104, 10 slip op. (6th Cir. Dec. 11, 2015) (citing *Cavanagh v. Ford Motor Co.*, No. 13–cv–4584, 2014 WL 2048571, at *5 (E.D.N.Y. May 19, 2014)); *Papike v. Tambrands Inc.*, 107 F.3d 737, 744 (9th Cir. 1997). Furthermore, notwithstanding their kitchen sink approach, Plaintiffs' laundry list of purported negligent acts falls squarely within the purview of a manufacturing (Ex. G, FAC, ¶ 102, subp. a, r-t), design (*id.*, ¶ 102, subp. a-c, g-j, m, q, w) and warning (*id.*, ¶ 102, subp. d-f, k, l, n-p, u, v) defect claim.

Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993). A plaintiff must plead these evidentiary facts and must explain why the alleged conduct or statements are fraudulent. *Illinois Nat. Ins. Co. v. Nordic PCL Constr., Inc.*, 870 F. Supp. 2d 1015, 1036-37 (D. Haw. 2012) (quoting *Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)).

In *Vess*, the court explained two situations in which a plaintiff—who has not asserted a cause of action specifically sounding in fraud—is nonetheless required to plead with particularity to satisfy Rule 9(b). *Vess*, 317 F.3d at 1103-04. Both situations arise in cases where fraud is not a necessary element of any claim asserted, but a plaintiff chooses, nonetheless, to allege in the complaint that the defendant has engaged in fraudulent conduct. *Id.* at 1103.

First, "the plaintiff may allege a unified course of fraudulent conduct and rely entirely on that course of conduct as the basis of a claim. In that event, the claim is said to be 'grounded in fraud' or to 'sound in fraud,' and the pleading of that claim as a whole must satisfy the particularity requirement of Rule 9(b)." *Id.* at 1103-04; *see also Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). Second, in other cases, a plaintiff may not allege a "unified course of fraudulent conduct" but nevertheless inserts allegations of defendant's fraudulent

conduct. *Vess*, at 1104. In those cases, only the allegations asserting fraudulent conduct must be pled with specificity as required by Rule 9(b). *Id.*[5]

Here, although Plaintiffs may not allege a "unified course of fraudulent conduct" throughout the Complaint, Plaintiffs plainly and repeatedly insert numerous allegations of purportedly fraudulent conduct, including:

- "In written information about the safety and risks of Eliquis, Defendants negligently **and fraudulently represented** to the medical and healthcare community, including Decedent's prescribing doctor, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Decedent and the public in general, that Eliquis had been tested and was found to be safe and effective for its indicated uses." Ex. G, FAC, ¶ 3 (emphasis added).
- "**Defendants concealed their knowledge** of Eliquis' defects from Decedent, the FDA, the public in general and the medical community, including Decedent's prescribing doctor." *id.*, ¶ 4 (emphasis added).
- **"These representations were made by Defendants with the intent of defrauding and deceiving Decedent**, the public in general, and the medical and healthcare community including

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[5] Notably, while negligent misrepresentation claims—based solely on negligent and not intentional or fraudulent conduct—are not *per se* governed by Rule 9(b), under Hawai`i law, when a claim is based on some fraudulent and some non-fraudulent conduct, the allegations of fraud are subject to Rule 9(b)'s heightened pleading requirements and may be dismissed if pled insufficiently. *Compare Illinois Nat. Ins. Co.*, 870 F. Supp. 2d at 1038-39 (dismissing allegations to the extent based on fraudulent conduct as insufficiently pled) *with Smallwood v. NCsoft Corp.*, 730 F. Supp. 2d 1213, 1231-32 (D. Haw. 2010) (heightened pleading standard does not apply to claims of exclusively negligent misrepresentations).

Decedent's prescribing doctor, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and purchase Eliquis, all of which **evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Decedent** herein." *id.*, ¶ 5 (emphasis added).

- ". . . Sadly, **Defendants and their agents committed fraud** in their conduct of the ARISTOTLE study, by concealing side effects which occurred in test users of Eliquis . . . ." *id.*, ¶ 26 (emphasis added).

- **"Upon information and belief**, **Defendants concealed** and failed to completely disclose their knowledge that Eliquis was associated with or could cause life-threatening bleeding as well as its knowledge that they had failed to fully test or study said risk." *id.*, ¶ 43 (emphasis added).[6]

- "Improperly **concealing and/or misrepresenting** information from the Decedent, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Eliquis compared to other forms of treatment for blood-thinning." *id.*, ¶ 102 (v) (emphasis added).

- "Punitive and/or exemplary damages for the **wanton, willful, fraudulent, reckless acts of the Defendants**, which constitute gross negligent [sic], as Defendants demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct." *id.*, Prayer for Relief, ¶ 3 (emphasis added).

Those conclusory allegations are plainly insufficient under Rule 9(b).

Plaintiffs do not allege any details of the misrepresentations, or the "who, what,

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[6] Allegations "on information and belief" are insufficient to satisfy Rule 9(b). *Illinois Nat.*, 870 F. Supp. 2d at 1037. Plaintiffs are obligated to set forth the facts that form the bases for the "belief." *Id.*

where, when, why and how" that are needed to satisfy Rule 9(b). As a result, Plaintiffs' allegations regarding fraudulent behavior on behalf of Defendants fail to satisfy the heightened pleading standards of Rule 9(b) and should be dismissed.

E. Plaintiffs' Claim for Punitive Damages Is Not Supported by Sufficient Factual Allegations.

In Hawai`i, punitive damages may be awarded in a product liability action based on strict liability or negligence only where a plaintiff proves the requisite aggravating conduct on the part of the defendant. *Masaki v. Gen. Motors Corp.*, 71 Haw. 1, 10-11 (1989) (quoting *Bright v. Quinn*, 20 Haw. 504, 512 (1911). Those aggravating factors include extreme scenarios where a party "'has acted wantonly or oppressively or with such malice as implies a spirit of mischief or criminal indifference to civil obligations'; or where there has been 'some wilful (sic) misconduct or that entire want of care which would raise the presumption of a conscious indifference to consequences.'" *Id.* at 12-13; *see also Ass'n of Apartment Owners of Newtown Meadows ex rel. Bd. of Dir. v. Venture 15, Inc.*, 115 Hawai`i 232, 297 (2007) (reciting aggravating factors needed for punitive damages award). Applicability of punitive damages always requires "a positive element of conscious wrongdoing," not merely inadvertence, mistake, or errors in judgment. *See Ass'n of Apartment Owners*, 115 Hawai`i at 297 (citing Restatement (Second) of Torts § 908).

Plaintiffs here insert boilerplate allegations that Defendants' conduct is "extreme and outrageous" and argue Plaintiffs should be entitled to punitive damages. *See* Ex. G, FAC, ¶¶ 75, 95, 109. Like Plaintiffs' other faulty claims, these too rely on conjecture and conclusory allegations rather than concrete, specific factual allegations. Further, Plaintiffs cannot point to any "positive element of wrongdoing," such as knowledge or action on the part of Defendants, to establish the conduct necessary to warrant punitive damages. Because the FAC does not allege specific facts demonstrating that any of the Defendants have acted with malice, oppression, or gross negligence, Plaintiffs cannot sustain a claim for punitive damages. *See Barnes v. Sea Hawai`i Rafting*, LLC, No. 13-00002, 2013 WL 6062527, at *8 (D. Haw. Nov. 15, 2013) (rejecting punitive damages claim because the complaint did not "set forth any specific factual allegations supporting" plaintiff's conclusory statements). For these reasons, Plaintiffs' prayer for punitive damages is wholly unsupported, and this Court should dismiss it as well.

IV. CONCLUSION

The bulk of Plaintiffs' First Amended Complaint should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). Counts I, II, and III purport to allege claims for a manufacturing defect. Plaintiffs have neglected to plead, however, the facts necessary to support their manufacturing defect claims—regardless of whether

those allegations sound in strict liability or negligence—and as such those claims should be dismissed. Counts I and II also purport to allege strict liability and negligent design defect claims, but under Hawai`i law, there is no viable design defect claim premised on the chemical composition of a prescription medication. At most, Plaintiffs' design defect claims should be limited to those based on the warnings accompanying the medication.

Not only are Plaintiffs' manufacturing defect claims factually deficient and their design defect claims deficient as a matter of law, but Plaintiffs' inclusion of sporadic allegations of fraud also lack the particularity required by Rule 9(b). These claims, too, should be dismissed. Finally, the First Amended Complaint purports to seek punitive damages, but Plaintiffs fail to assert factual allegations and conduct that could support such damages.

DATED: Honolulu, Hawai`i, January 26, 2016.

/s/ *JOHN-ANDERSON L. MEYER*
PAUL ALSTON
JOHN-ANDERSON L. MEYER

Attorneys for Defendants
BRISTOL-MYERS SQUIBB COMPANY
and PFIZER INC.